K103797 (pg 1/1)

MAY 2 0 2011

510(k) Summary
for the
K2M CoCr Wire

This 510(k) summary for the K2M CoCr Wire is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :
K2M, Inc.
751 Miller Drive SE,
Suite F1
Leesburg, VA 20175

Contact Person :
Nancy Giezen
K2M, Inc.
Telephone: 703-777-3155

Date Prepared: 12/23/10

2. Tradename:	K2M CoCr Wire
Common Name:	Orthopedic Wire
Classification Name:	Bone Fixation Cerclage (21CFR 888.3010)
Device Product Code:	87 JDQ
Regulatory Class:	Class II

3. Predicate or legally marketed devices which are substantially equivalent :

- Howmedica Orthopedic Wire (K031127)

4. Description of the device:

K2M CoCr Wires are single stranded implants, with a diameter of 1.0mm (18 gauge).

Materials: The wires are manufactured from Cobalt Chrome per ASTM standards.

Function: K2M CoCr Wires are single use devices intended for the stabilization of bony segments.

5. Intended Use:

K2M CoCr Wires are intended for:

- Bone fracture fixation
- Osteotomy
- Arthrodesis
- Correction of deformity
- Revision procedures when other treatments or devices have been unsuccessful, and,
- Bone reconstruction procedures

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

The K2M CoCr Wires are manufactured in compliance with ASTM F1091. There are no significant differences between the K2M wire and other wires currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

K2M, Inc.
% Nancy Giezen
751 Miller Dr. SE
Leesburg, VA 20175

MAY 2 0 2011

Re: K103797
Trade/Device Name: K2M CoCr Wire
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: May 11, 2011
Received: May 13, 2011

Dear Ms. Giezen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103797 (pg 1/1)

Device Name: K2M CoCr Wire

Indications for Use:

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- Bone fracture fixation
- Osteotomy
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- Revision procedures when other treatments or devices have been unsuccessful, and,
- Bone reconstruction procedures

Prescription Use X AND/OR Over-the-counter Use __
~~(Part 21 CFR 801 Subpart D)~~ ~~(21 CFR 801 Subpart C)~~

(PLEASE DO NOT WRITE BELOW THIS-LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. McKeever

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103797